

**Remarks/Arguments**

Claims 57, 58 and 76 have been canceled. Claims 62-75, 77 and 78 are withdrawn. New claim 79-81 have been added. Claims 59, 60 and 61 have been amended to depend from the new claims. The new claims do not introduce new matter and are fully supported by the specification and claims as originally filed. The new claims are presented to clarify the scope of the claimed inventions and to address issues raised in the pending Office Action.

A new oath/declaration accompanies the present response. In addition, a terminal disclaimer accompanies the present response. Entry of the amendment is respectfully requested. Upon entry of the present amendment, claims 59-61 and 79-81 will be pending and at issue.

**I. Rejection Under 35 U.S.C. §112 First Paragraph**

*Written Description*

Claims 57-61 and 76 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This rejection is moot with regard to canceled claims 57, 58 and 76. Applicants traverse this rejection as it may apply to the amended claims and new claims.

To advance prosecution, new claims 79-81 no longer recite the “comprising” language objected to by the Office Action. Despite the elimination of this language, and in contrast to the assertion by the Office Action, the written description component of §112 does not require Applicants to “define” all the members of a claimed genus nor must all members of that genus be “biologically functional.” Accordingly, the new claims are presented solely to clarify the scope of the claimed invention and to expedite allowance of the pending claims.

The Office Action also alleges that the specification lacks adequate written description with regard to the “linker.” Applicants note that the “linker” language recited in the new claims is similar to the language appearing in the allowed claims of application Serial No. 08/594,575, or in the issued claims presented in U.S. Patent No. 5,981,200, both of which are related to the

present application. It is not clear why such language succeeds in satisfying the written description requirement for the claims in the parent applications, but fails to do so for the claims presented in their progeny. Applicants maintain that the “linker” language included in the new claims clearly allows persons of ordinary skill in the art to recognize that Applicants were in possession of the claimed invention.

In view of the new claims and in light of the above discussion, Applicants request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

*Enablement*

Claims 57-61 and 76 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly non-enabled. This rejection is moot with regard to canceled claims 57, 58 and 76. Applicants traverse this rejection as it may apply to the amended claims and new claims.

As noted above, new claims 79-81 have been added to expedite allowance of the pending claims. Applicants submit that the language recited in the new claims render the present rejection moot.

The Office Action alleges that the specification is not enabled for “linkers that are fluorescent” nor for linkers that fall outside a range of 5-50 amino acids in length. As previously noted, the “linker” language recited in the new claims is similar to the language appearing in the allowed claims of application Serial No. 08/594,575, or in the issued claims presented in U.S. Patent No. 5,981,200, both of which are related to the present application. The Office Action appears to take the position that, since the specification allegedly fails to enable “fluorescent” linkers, the pending claims should specifically exclude everything that the linker can not be (i.e., “linkers that are not fluorescent”). Alternatively, the Office Action appears to suggest that that Applicants should limit the linker to a specific length (i.e., “linkers that are between 5 and 50 amino acids in length”).

Applicants respectfully submit that the written disclosure of the instant application is supplemented by the knowledge held by one of ordinary skill in the art. The skilled artisan is one who is knowledgeable about basic laboratory/research protocols. It is well settled law that

an Applicant need not include in the disclosure information that is well known in the art. Applicants have provided exemplary methodology for designing a linker that is operably integrated in to the claimed tandem fluorescent protein construct. It is well within the capabilities of the skilled artisan, at the time the application was filed, to take such examples and modify the size and/or composition of the linker to obtain a construct of the invention. The skilled artisan can manufacture various linkers that can be used in the claimed construct without undue experimentation because he/she will recognize is unnecessary to test every possible linker composition, or linker length, that can, in theory, be used in the claimed construct. Accordingly, the claimed construct should not be limited to including a linker having the an exemplary composition and/or length set forth in the specification because the skilled artisan can easily determine the optimal linker length for use in the claimed construct.

In view of the new claims and in light of the above discussion, Applicants request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

## **II. Rejection Under 35 U.S.C. §112 Second Paragraph**

Claims 57-61 and 76 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is moot with regard to canceled claims 57, 58 and 76. While Applicants traverse this rejection, Applicants submit that the presentation of new claims 79, 80 and 81, and the amendments to claims 59, 60 and 61, render the rejection moot. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

## **III. Rejection Under Obviousness-Type Double-Patenting**

Claims 57-61 and 76 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4, 7-12 and 14 of U.S. Patent No. 5,981,200. Applicant respectfully traverses this rejection and notes that rejection is moot with respect to canceled claims 57, 58 and 76.

In re Application of  
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Serial No.: 10/057,505  
Filed: January 25, 2002  
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PATENT  
Attorney Docket No. REGEN1260-3

The present application is a continuation of U.S. Serial No. 09/396,003, filed September 13, 1999, which is a continuation of U.S. Serial No. 08/792,553, filed January 31, 1997 (now U.S. Patent No. 5,981,200), which is a continuation-in-part of U.S. Serial No. 08/594,575, filed January 31, 1996. Applicants note that the non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. Given that the present application claims priority to the filing date of the patent providing the basis for this rejection, the Applicants are clearly not seeking to extend the "right to exclude" based any patent resulting from the present application. Nevertheless, a terminal disclaimer in compliance with 37 CFR 1.321(c) accompanies the present response. Accordingly, Applicants request withdrawal of this rejection.

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. Please apply any charges not covered, or any credits, to Deposit Account 50-1355. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

Respectfully submitted,

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Appendix A  
 TABLE I

<u>Clone</u>	<u>Mutation(s)</u>	<u>Excitation max (nm)</u>	<u>Emission max (nm)</u>	<u>Extinct. Coefficient (M<sup>-1</sup>cm<sup>-4</sup>)</u>	<u>Quantum yield</u>
<i>Wild Type</i>	none	395 (475)	508	21,000 (7,150)	0.77
<i>P4</i>	Y66H	383	447	13,500	0.21
<i>P4-3</i>	Y66H; YI45F	381	445	14,000	0.38
<i>W7</i>	Y66W; N146I M153T V163A N212K	433 (453)	475 (501)	18,000 (17,000)	0.67
<i>W2</i>	Y66W; I123V Y145H H148R M153T V163A N212K	432 (453)	480	10,000 (9,600)	0.72
<i>S65T</i>	S65T	489	511	39,200	0.68
<i>P4-1</i>	S65T; M153A K238E	504 (396)	514	14,500 (8,600)	0.53
<i>S65A</i>	S65A	471	504		
<i>S65C</i>	S65C	479	507		
<i>S65L</i>	S65L	484	510		
<i>Y66F</i>	Y66F	360	442		
<i>Y66W</i>	Y66W	458	480		
<i>10c</i>	S65G; V68L S72A; T203Y	513	527		
<i>W1B</i>	F64L; S65T Y66W; N146I M153T V163A N212K	432 (453)	476 (503)		
<i>Emerald</i>	S65T; S72A N149K M153T I167T	487	508		
<i>Sapphire</i>	S72A; Y145F T203I	395	511		